FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research

Joint Meeting of the Arthritis Advisory Committee (AAC)
and the Drug Safety and Risk Management Advisory Committee (DSaRM)

May 12, 2010

Hilton Washington DC/Silver Spring, the Ballrooms, 8727 Colesville Road
Silver Spring, Maryland

AGENDA

The committees will discuss new drug application (NDA) 22-478, naproxcinod 375 milligram capsules, a non-steroidal anti-inflammatory drug (NSAID) product by NicOx S.A., indicated for treatment of the signs and symptoms of osteoarthritis.

8:00 a.m.	Call to Order Introduction of Committee	**Kathleen O'Neil, MD** Chair, AAC
	Conflict of Interest Statement	**Anuja Patel, MPH** Designated Federal Officer
8:10 a.m.	Opening Remarks	**Robert Shibuya, MD** Clinical Team Leader Division of Anesthesia and Analgesia Products (DAAP), CDER/FDA
8:15 a.m.	**Sponsor Presentations**	
	Introduction	**Elizabeth Robinson, PhD** President, NicOx Research Institute Srl
	Rationale for Development of Naproxcinod	**Marc Hochberg, MD** Professor of Medicine Head, Division of Rheumatology and Clinical Immunology University of Maryland School of Medicine
	Clinical Efficacy and Safety	**Pascal Pfister, MD, MFPM** NicOx, Chief Scientific Officer Head of Research & Development
	Blood Pressure Overview	**William White, MD** Professor and Chief Division of Hypertension and Clinical Pharmacology, Calhoun Cardiology Center University of Connecticut School of Medicine, Farmington, Connecticut
	Importance of SBP Levels in Patients with OA	**Michael Weber, MD** Professor of Medicine SUNY Downstate Medical College of Medicine Brooklyn, New York
	Benefit Risk of Naproxcinod	**Marc Hochberg, MD**

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Agenda continued…

9:45 a.m.	Clarifying Questions for Sponsor Presenters	
10:05 a.m.	Break	
10:20 a.m.	**FDA Presentations**	
10:20 a.m.	Naproxcinod: FDA Efficacy and Safety Review	**Jacqueline Spaulding, MD, MPH** Medical Officer DAAP, CDER/FDA **Feng Li, PhD** Biometrics Reviewer Office of Biostatistics CDER/FDA
10:40 a.m.	Cardiovascular Summary Review	**Suchitra Balakrishnan, MD, PhD** Medical Officer Division of Cardiovascular and Renal Products CDER/FDA
11:05 a.m.	Review of Endoscopy Studies	**Wen-Yi Gao, MD, PhD** Medical Officer Division of Gastroenterology Products CDER/FDA
11:20 a.m.	Pharmacokinetics of Naproxcinod and Naproxen	**Wei Qiu, PhD** Clinical Pharmacology Reviewer Office of Clinical Pharmacology CDER/FDA
11:30 a.m.	Clarifying Questions for FDA Presenters	
12:00 p.m.	Lunch Break	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Committee Discussion	
3:30 p.m.	Voting Questions to the Committee (Vote)	
4:30 p.m.	Adjourn	